The Consumer Voice in Europe

BEUC COMMENTS TO

PUBLIC CONSULTATION FOR LEGISLATIVE PROPOSAL ON A EUROPEAN HEALTH DATA SPACE

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Why it matters to consumers

BEUC, The European Consumer Organisation appreciates the opportunity to provide input to the European Commission's (EC) ongoing public consultation on a European Health Data Space (EHDS). We hope that the consultation will help to ensure that sensitive data of European patients and consumers used for scientific advancements is well protected and serves societal interests.

We call on the European Commission to address in the upcoming legislative proposal the following issues:

1. Differences in European and national competences in healthcare and their impact on EHDS

According to the EU Treaties, the Member States (MS) have the competence to organise their health policy, as well as the delivery of healthcare services. EU Member States have diverse healthcare systems, with distinctive management types (e.g. centralised, decentralised). Such differences in national health policies reflect various diverse political, historical, and socio-economic traditions. These differences inevitably impact on how such systems can interact with each other, and this significantly complicates the creation of the EHDS which requires common rules and harmonisation of approaches on standards, procedures, medical research, and patient rights. Soft law (e.g. guidelines) will not solve the issue, as the national approaches are guided by binding provisions and the possibilities for the EU to introduce common legal rules are limited to cross-border healthcare provisions.

Recommendations:

- Based on a thorough assessment of a future EHDS' potential limitations, the EC should identify options to promote harmonization of approaches, considering the complexities and divergences in national systems.
- The EC should establish a common legal approach to EHDS when it comes to cross-border research and healthcare services.

2. Diverse rules on health data

The General Data Protection Regulation[1] (GDPR) provides a solid framework for personal data protection and removes most of the previously existing fragmentation at the national level. However, when it comes to genetic, biomedical and health data the GDPR has several derogations allowing MS to specify their own rules. Such derogations may create obstacles for developing a common regime for health data uses, as they allow MS to apply diverse approaches on:

[1] https://eur-lex.europa.eu/eli/reg/2016/679/oj

- ***Data processing for scientific research and medical purposes****:* MS can provide exceptions to some of the data subject rights – e.g. access, rectification, right to object processing.
- ***Explicit consent****:* national law can include provisions which would not allow lifting the general prohibition on processing of health data even with explicit consent. For instance, in Greece processing of genetic data for insurance purposes is prohibited even with data subject's consent.[2] Even though such provisions are justified, different rules in other countries might imply inequal levels of consumer protection and have an effect on the representativeness of the health data that is processed.
- ***Re-use of data*****:** countries have different rules on the re-use of health data. E.g. countries define what constitutes 'scientific research' in different ways. In some countries there is no definition at all (Finland, Germany). These MS define requirements for research through regulation of responsible authorities.[3] This has implications on what data can be available for scientific research within the EHDS from different countries.

Even though some fragmentation is present in national approaches to personal health data, the current framework is comprehensive compared to the nearly non-existent rules for non-personal health data. The upcoming Data Governance Act and Data Act have the potential to establish a clearer framework for governance and access to non-personal data. However, special attention must be paid to health data, as this category is particularly sensitive, and the fact that this data has been anonymised and/or aggregated does not completely remove privacy risks.

Recommendations:

- The EC must consider binding measures to ensure higher convergence of the MS rules on personal health and biomedical data uses, within the limits of its competences, e.g. when it comes to the cross-border research and medical services.
- The EHDS legislative proposal must include a comprehensive framework for health data, potentially introducing additional safeguards, strict standards for data pseudonymisation and anonymisation and clarifying rights and obligations of parties processing such data.

3. Artificial intelligence and EHDS

Once established, data available through EHDS might be used for developing and training artificial intelligence (AI) based tools and services. Quality of AI-based devices and services will largely depend on the quality of initially collected data. Any potential errors, biases and inaccuracies in initial datasets will be further multiplied through the algorithm.
For instance, IBM Watson for Oncology is one of the best-known AI examples of why data quality matters. IBM began selling Watson to recommend the best cancer treatments to doctors around the world. Practical experience, however, showed that Watson for Oncology often resulted in unsafe and incorrect treatment recommendations. Watson's algorithm was largely based on the data of American patients and care methods, and it created a bias against patients at foreign hospitals, as their methods were not considered for the initial coding of algorithm.[4]

[2] D. Gabel, T.Hickman 'GDPR guide to national implementation', White& Case, November 2019.
[3] J. Meszaros et all 'The interaction of the medical device regulation and the GDPR', Cambridge University Press. 2020.
[4] Statnews, IBM pitched its Watson supercomputer as a revolution in cancer care. It's nowhere close, September 2017, https://www.statnews.com/2017/09/05/watson-ibm-cancer/

Furthermore, when it comes to AI uses by healthcare professionals, responsibility and liability chains are not always clear, which leaves patients and consumers more vulnerable to effects of malpractice.

Recommendations:

- The EC should develop clear requirements on data quality and accuracy, as well as methods to check data for potential biases within the EHDS.
- The EC must establish clear rules for healthcare professionals', developers' responsibility and liability when AI is involved into medical decision-making and healthcare services provision.
- The EC must ensure strong horizontal framework for AI through AI Act, complemented by a sector-specific rules for AI in healthcare.
- Patients and consumers must have enforceable rights when it comes to uses of AI based tools in healthcare.

ENDS

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